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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/484,809	01/18/2000	Julio J. Santos-Munne	4204.3-US	1128

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[REDACTED] EXAMINER

MILLER, RYAN J

ART UNIT	PAPER NUMBER
2621	11

DATE MAILED: 06/09/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>
	09/484,809	SANTOS-MUNNE ET AL.
	<b>Examiner</b>	<b>Art Unit</b>
	Ryan J. Miller	2621

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 03 April 2003.
- 2a) This action is FINAL.                  2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-5 and 11-26 is/are pending in the application.
- 4a) Of the above claim(s) 1-5, 25 and 26 is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 11-24 is/are rejected. 7
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on 18 January 2000 is/are: a) accepted or b) objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some \* c) None of:
1. Certified copies of the priority documents have been received.
  2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                               | 4) <input checked="" type="checkbox"/> Interview Summary (PTO-413) Paper No(s). <u>10</u> . |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)           | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)                 |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ . | 6) <input type="checkbox"/> Other: _____ .  |

## **DETAILED ACTION**

### ***Response to Amendment***

1. The amendment received on April 3, 2003 has been entered in full. An action on its merits follows.

### ***Election/Restrictions***

2. Restriction to one of the following inventions is required under 35 U.S.C. 121:
- I. Claims 1-5, drawn to a method for determining the distance between two points corresponding to an anatomical feature using two or more fluoroscopic images, classified in class 382, subclass 128 (Image Analysis, Biomedical applications).
  - II. Claims 11-24, drawn to a method for displaying a graphical representation of an object in fluoroscopic images, classified in class 345, subclass 700 (Operator Interface Processing, Operator interface (i.e. graphical user interface)).
  - III. Claims 25-26, drawn to an apparatus for determining the rate of velocity and/or acceleration of an object in the human body, classified in class 382, subclass 107 (Image Analysis, Motion or velocity measuring).

The inventions are distinct, each from the other because of the following reasons:

3. Inventions I, II, and III are related as subcombinations disclosed as usable together in a single combination. The subcombinations are distinct from each other if they are shown to be separately usable. In the instant case, invention II has separate utility such as displaying a graphical representation of a virtual surgical object, instead of determining the dimensions of an anatomical feature of interest, for the purpose of planning surgery. Invention III has separate utility, that is not related to determining the distance between two points of an anatomical

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structure (Group I) or displaying a graphical representation of an object (Group II), such as determining the blood flow rate in a human. See MPEP § 806.05(d). Given that Invention III is withdrawn due to the original presentation, applicant is now required to elect either Invention I or Invention II.

4. Newly submitted claims 25 and 26 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: Claims 25 and 26 are drawn towards a system for determining the velocity and or the acceleration of an object, whereas as originally claimed invention is drawn toward the determination of the distance between two points corresponding to an anatomical object in two or more fluoroscopic images.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 25 and 26 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

5. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

6. During a telephone conversation with Marc Hubbard (Reg. No. 32,506) on June 5, 2003 a provisional election was made with traverse to prosecute the invention of Group II, claims 11-24. Affirmation of this election must be made by applicant in replying to this Office action. Claims 1-5 and 25-26 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

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7. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

*Drawings*

8. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they include the following reference sign(s) not mentioned in the description: (a) “103” in Fig. 4, (b)“300” referring to a screen in Fig. 6, (c) “606” referring to a projected stent in Fig. 9, and (d) “606” in Fig. 7. A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

*Claim Objections*

9. The following quotation of 37 CFR § 1.75(d)(1) are the basis of objection:

(d)(1) The claim or claims must conform to the invention as set forth in the remainder of the specification and the terms and phrases used in the claims must find clear support or antecedent basis in the description so that the meaning of the terms in the claims may be ascertainable by reference to the description. (See § 1.58(a)).

10. Claim 15 is objected to under 37 CFR § 1.75(d)(1) as failing to particularly point out and distinctly claim the subject matter which the applicant regards as his invention or discovery. Claim 15 calls for the object to be comprised of a “non-linear line”. There is no antecedent basis for the term “non-linear line” in the specification. Does the applicant mean that a “non-linear line” is a “curved line” as described at specification page 2, line16? The examiner has interpreted this limitation as a curved line.

***Claim Rejections - 35 USC § 112***

11. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

12. Claims 11, 14-16, 19, and 22 rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The invention as originally filed has three embodiments. The first embodiment, described on page 2, lines 3-26, page 7, line 24 – page 10, line 9, and in Fig. 4, discloses a method of determining the dimensions of an anatomical feature by determining the distance of a line specified by at least two points in a fluoroscopic image. The second embodiment, described on page 3, lines 1-30, page 7, line 28 – page 13, line 9, and in Fig. 6, discloses a method of displaying and manipulating a graphical representation of a virtual surgical object in a fluoroscopic image. The third embodiment, for determining the velocity of an object, is not pertinent in this rejection. Claims 11, 19, and 22 are drawn to the second embodiment. However, the last step of these claims, “measuring a dimension of the object” is not supported by the original disclosure as being a step executed by the second embodiment. As can be seen in Fig. 6 (i.e. corresponding to the second embodiment), the first three steps of the claims are clearly disclosed. However, the step of “measuring a dimension of the object” is drawn to the first embodiment (i.e. step 112 of Fig. 4, which is drawn to the first embodiment). The claim appears to be a mix of the disclosed embodiments that does not have literal support in the

original disclosure. Therefore, the examiner assumes that this limitation of the claim is drawn toward step 414 of Fig. 6, which updates the size/position/orientation of the projected surgical object in the images. The examiner interprets this limitation as “adjusting a dimension of the object” for examination purposes.

Regarding claims 14-16, these claims depend from claim 11. Claim 11, as discussed above appears to be drawn to the second embodiment; however, claims 14-16 are drawn to the first embodiment. This mix of the embodiments is not supported by the original disclosure. Appropriate correction of this issue is required.

***Claim Rejections - 35 USC § 102***

13. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

14. Claims 11-17 and 19-24 are rejected under 35 U.S.C. 102(b) as being anticipated by Peshkin et al. (U.S. Patent No. 5,799,055 A).

As applied to claim 11, Peshkin et al. discloses a computer-assisted method for determining a dimension of an anatomical feature, the method comprising: displaying a first fluoroscopic image taken of an anatomical feature of interest from a first angle (see Figs. 1, 3a, and column 5, lines 14-29: The reference describes using a fluoroscope to take an image of a patient's body and then displaying the image on graphics monitor 48 (i.e. displaying a first fluoroscopic image taken of an anatomical feature of interest from a first angle).) and a second fluoroscopic image taken from a second angle of the anatomical feature of interest (see Figs. 1,

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3b, and column 5, lines 30-32: The reference discloses obtaining a second image of the patient's body from a different angle and displaying it on graphics display 50 from an angle different from the first image.), the first and second images being registered with respect to a common three-dimensional coordinate system (see column 5, lines 24-29 and lines 35-42: The reference describes registering each of the images to the three-dimensional coordinates of the fiducials in the image.); defining in the three-dimensional coordinate system an object by receiving indications of the position of the object with respect to the first and second fluoroscopic images (see column 5, lines 46-49: The reference describes receiving a user's input to select the position, length, and angles (i.e. defining in the three-dimensional coordinate system) of a virtual guidewire (i.e. an object). The user input of the position, length, and angles corresponds to receiving indications of the position of the object with respect to the first and second fluoroscopic images.); displaying in the first and second fluoroscopic images graphical representations of the object projected into the first and second fluoroscopic images (see column 5, lines 49-54: The reference describes drawing a segment that represents the virtual guidewire (i.e. a graphical representation of the object) and that the projected virtual guidewire corresponds geometrically to the same three-dimensional segment in space.); and adjusting a dimension of the object (see column 5, lines 60-61: The reference describes that the user can change the length (i.e. adjust the dimension) of the virtual guidewire (i.e. the object.).).

As applied to claim 12, which is representative of claim 13, Peshkin et al. discloses automatically updating the positions of the graphical representations of the object projected into the first and second fluoroscopic images based on a change in the position of the object (see column 5, line 66 – column 6, line 4: The reference describes that the user can change the

sagittal, transverse, or coronal angle(s) of the virtual guidewire and that the system will automatically update the orientation (i.e. position) of the virtual guidewire based on the new angles.).

As applied to claim 14, Peshkin et al. discloses that the object is comprised of at least two points (see Fig. 3b: Projected guidewire 68 (i.e. the object) consists of entry point 64 and bottom point 66.).

As applied to claim 15, Peshkin et al. discloses that the object is further comprised of a line connecting at least two points specified with respect to the first and second fluoroscopic images (see Fig. 3b: From this figure it is clear that the projected guidewire 68 (i.e. the object) comprises a line connecting the two points.).

As applied to claim 16, Peshkin et al. discloses that the object is further comprised of a non-linear line connecting at least two points specified with respect to the first and second fluoroscopic images (see column 17, lines 1-10: The reference describes that the computer 40 can draw a curve (i.e. non-linear line) as a guide for the user to enter the projected guidewire.).

As applied to claim 17, Peshkin et al. discloses that the object is three-dimensional (see column 5, lines 51-54: The reference describes that the virtual guidewire (i.e. the object) is a three-dimensional segment in space.).

As applied to claims 19-21, which merely call for a computer readable storage medium for storing the program instructions to perform the method of claims 11-13, Peshkin et al. discloses such a computer readable storage medium since all of the processing in Peshkin et al. is performed by computer (see column 7, lines 52-55: The reference describes that the system is

controlled by a computer, which includes a microprocessor, internal RAM, and a hard disk drive.).

As applied to claims 22-24, which merely call for an apparatus for performing the method of claims 11-13, Peshkin et al. discloses such an apparatus as can be seen in Fig. 1 of the reference.

### ***Claim Rejections - 35 USC § 103***

15. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

16. Claim 18 is rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Peshkin et al. (U.S. Patent No. 5,799,055 A) and Alt (U.S. Patent No. 6,159,142 A). The arguments as to the relevance of Peshkin et al. in paragraph 14 above are incorporated herein.

Claim 18 calls for the object to represent a stent. A stent is absent from Peshkin et al. but is clearly shown in Alt (see column 1, lines 57-64: The describes a process of implanting a stent under fluoroscopic observation).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to modify Peshkin et al. by adding the stent of Alt because the use of fluoroscopic imaging when implanting stents is widespread. Therefore, a method for planning this surgery through the use of fluoroscopic images and virtual stents is very important for increasing the safety and reliability of such procedures.

***Response to Arguments***

**Prior Art Rejections**

**35 U.S.C. 102 rejections**

Applicant's arguments with respect to claims 1-5 regarding Kano (U.S. Patent No. 4,099,880) have been considered but are moot since these claims are non-elected claims.

***Conclusion***

17. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

18. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ryan J. Miller whose telephone number is (703) 306-4142. The examiner can normally be reached on M-F 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Leo Boudreau can be reached on (703) 305-4706. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9314.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 305-4750.

Ryan J. Miller  
Examiner  
Art Unit 2621

*rym*  
Ryan J. Miller  
June 6, 2003

*Brian Werner*  
BRIAN WERNER  
PRIMARY EXAMINER